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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/737,026

12/16/2003

Steven N. Roe

7404-548

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10/20/2006

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/737,026 | Applicant(s) ROE, STEVEN N. | |
| | Examiner Helen Nguyen | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13, 17-25, 27-29, and 31-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 17-25, 27-29, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 8/08/2006. Amendments to the specification and Claim 22 are accepted, thus overcoming the previous objections. Claims 10 and 22 are amended. Claims 31-32 are new. **Claims 10-13, 17-25, 27-29, and 31-32** remain pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 10-13, 17-25, 27-29** are rejected under 35 U.S.C. 102(e) as being anticipated by Sakata et al (US Pat No. 20040215224).

4. In regard to **Claims 10, 24, 27-28, and 31**, Sakata et al disclose a body fluid sampling device best seen in Figure 2 comprising:

a lancet (3) configured to form an incision in skin;

a sampling mechanism, referred to as "analysis sensor" (4), having a sampling end defined as the left side of said sampling mechanism, disposed proximal to the lancet that is moveable between a first position over the incision, best seen in Figure 20, and a second position

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where the sample end is located farther away from the incision point defined at the same spot not including the skin bulge, best seen in Figure 19;

a deflection mechanism, referred to as "sensor holder" (7B), engageable with the sampling mechanism to deflect the sampling end of the sampling mechanism from the first position to the second position in order to allow the lancet to form the incision, best seen in Figure 19-20;

wherein at least a portion of the sampling mechanism is resilient because said sampling mechanism is movable from a first position to a second position, thus said sampling mechanism can also return to the first position after the incision is formed.

5. In regard to **Claims 11-13, and 19**, Sakata et al disclose the sampling mechanism (4) as a test strip fluid collection element that is resilient, as evidenced by the range of movement shown in Figures 19-20.

6. In regard to **Claim 17, 25, and 29**, Sakata et al disclose the deflection mechanism as a cam arm, referred to as "sensor holder" (7B) best seen in Figure 19, coupled to the lancet and capable of moving in unison with the lancet to deflect the test strip as described above.

7. In regards to **Claim 18**, Sakata et al disclose the cam arm (7B) has an angled surface, referred to as "stopper" (77a) best seen in Figure 19-20 that is engageable with the sampling mechanism (4) to deflect the sampling mechanism as described above.

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8. In regards to **Claim 20**, Sakata et al disclose a holder, referred to as "housing" (2).

defining:

a cam arm cavity, which the cam arm (7B) is slidably received, best seen in Figure 19 right side;

a fluid collection element cavity in which the fluid collection element (4) is received, best seen in Figure 19;

wherein the cam arm cavity intersects the fluid collection element cavity in that said cam arm cavity resides directly beside said fluid collection cavity.

9. In regards to **Claim 21**, Sakata et al disclose the holder (2) defining:

a lancet cavity, referred to as "cylindrical housing" (20), in which the lancet (3) is slidably received, best seen in Figure 19;

a deflection cavity in which the fluid collection element is able to deflect as described above, best seen in Figures 19-20.

10. In regards to **Claim 22-23 and 32**, Sakata et al disclose the sampling end portion of said fluid collection element (4) angled at an acute angle relative to the lancet (3), as seen in Figure 19, to allow the cam arm (7B) to deflect the fluid collection element before the lancet is able to strike the fluid collection element, as described above.

Response to Arguments

11. Applicant's arguments with respect to **Claims 10-13, 17-25, and 27-29** have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

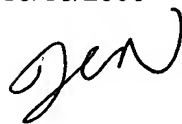
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
10/16/2006



HENDERBURG
PATENT EXAMINER
10/16/2006